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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/896,052 | 06/29/2001 | Frank J. Bunick | MCP-281 | 9476 |

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| EXAMINER |
|---|
| OH, SIMON J |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 04/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/896,052 | Applicant(s) BUNICK ET AL. | |
|---|---|---|---|
| | Examiner Simon J. Oh | Art Unit 1615 | |

*-- The MAILING DATE of this communication appears on the cover sh et with th correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Objections*

1. Claims 5 and 10 are objected to because of the following informalities: In claim 5, the word "gelatin" is spelled incorrectly. There is a period missing at the end of Claim 10. Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Pat. No. 6,060,078) in view of Mehta (U.S. Pat. No. 4,800,087).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Mehta teaches a chewable, taste-masked pharmaceutical dosage form, preferably in the form of a tablet (See Column 1, Lines 6-28). The components of this dosage form consist of

taste-masked microcapsules, which may then be prepared as chewable tablets. The microcapsules themselves comprise a polymeric coating that masks the taste of the active ingredient, and a pharmaceutical core (See Column 4, Lines 4-12; and Examples 1 and 2). Acetaminophen and ibuprofen are listed among suitable drugs for use in the reference (See Column 7, Lines 31-48; and Claims 11 and 12). Diluents acceptable for use in the microcapsule core include gelatin (See Column 7, Line 59 to Column 8, Line 12). In the given examples, the preferred size of the uncoated acetaminophen particles used lies in the range of 150 to 300 microns (See Column 10, Lines 45-47); and a rationale for such a limitation is given as well (See Column 2, Lines 18-35). The reference also teaches that the coated pharmaceutical cores may then be encapsulated in a hard gelatin capsule or further coated with candy (See Column 9, Lines 35-40).

Mehta does not teach the use of a pectin-based core.

Lee teaches a chewable pharmaceutical dosage form consisting of a core containing an active ingredient, and an outer layer (See Figure 2). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See Column 2, Lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and hardness property in the dosage form (See Column 2, Lines 59-61). The outer layer may take a variety of forms, including hard candy (See Column 2, Lines 34-42). Acetaminophen is listed as a possible active ingredient in core (See Column 2, Lines 9-18).

In regards to the limitation of the weight ratio of the drug particles to the outer shell, the examiner sees no criticality in such a feature. The examiner is of the opinion that the inventions of the prior art perform their intended use, that is, the taste-masking and delivery of active

substances, without explicitly possessing such characteristics. Similarly, the examiner is of the opinion that the brittleness limitation presented in Claim 6 is also not critical for the same reason.

It would be obvious to one of ordinary skill in the art to combine the teachings of Mehta and Lee in order to produce a chewable dosage form, consisting of a brittle outer shell and a soft core, which masks the taste of the bitter active ingredients such as acetaminophen and ibuprofen; provides a pleasant mouth-feel; and is convenient to consume, thereby increasing the likelihood of patient compliance.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Simon J. Oh
Patent Examiner
AU 1615

sjo
March 29, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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